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REPORT DOCUMENTATION PAGE OMB No. 0704-0188 Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 125 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503. 1. AGENCY USE ONLY (Leave blank) 2. REPORT DATE 3. REPORT TYPE AND DATES COVERED November 1997 Annual (30 Sep 96 - 31 Oct 97) 4. TITLE AND SUBTITLE 5. FUNDING NUMBERS National Rehabilitation Hospital Assistive Technology DAMD17-94-V-4036 Research Center 6. AUTHOR(S) John Toerge, D.O. 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) 8. PERFORMING ORGANIZATION National Rehabilitation Hospital REPORT NUMBER Washington, DC 20010-2949 9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES) 10. SPONSORING/MONITORING Commander AGENCY REPORT NUMBER U.S. Army Medical Research and Materiel Command Fort Detrick, Frederick, MD 21702-5012 11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY STATEMENT 12b. DISTRIBUTION CODE Distribution authorized to U.S. Government agencies only (proprietary information, Dec 97). Other requests for this document shall be referred to U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, Maryland 21702-5012. 13. ABSTRACT (Maximum 200 Assistive Technology Research Center. The Cognition and Performance Enhancement group reports on seven projects while the Rehabilitation Engineering group submits The common theme in all the projects is application of technologies and methods developed or heavily used by the military to enhancement of medical rehabilitation and independent living for people with disabilities. Particular emphases include investigation of the ANAM psychometric battery; application of ANAM and other instrumented measurement to detecting and characterizing concussion; investigation of the cognitive effects of ginkgo on stroke patients; application and evaluation of virtual reality technologies; design of new composite long leg braces as well as assistive devices for exercise, biofeedback and recreation; and studies of gait and how it loads lower extremity orthotics and is altered by surgery, 14. SUBJECT TERMS 15. NUMBER OF PAGES

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FOREWORD

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A. INTRODUCTION

In this report, we provide status information on a number of projects that began and/or were carried out by the National Rehabilitation Hospital's Assistive Technology Research Center (ATRC) in year three of our cooperative agreement # DAMD17-94-V-4036. This document also contains revised plans for year four activities which were provided to our designated project officer, Fred Hegge, Ph.D., in a meeting that took place October 16, 1997.

ATRC activities are directed by a senior management team comprising Michael Rosen, PhD and Joseph Bleiberg, PhD, co-principal investigators; John Toerge, DO, medical director of the ATRC; Jack Winters, PhD, director of Catholic University support for the ATRC; and Sabrina Smith, MHA, grant manager of the ATRC. This group meets regularly to review progress on ATRC goals and objectives.

The ATRC is divided into two main components: the Assistive Technology Transfer program and the Cognitive Performance Enhancement program. This report will reflect upon activities carried out by each of these programs and will discuss future projects charted for year four.

B. SENIOR MANAGEMENT CHANGES

The senior management team changed recently as a result of a team member leaving NRH. William Peterson, MS, resigned his position as Director of Rehab Engineering and the ATRC. Michael Rosen, PhD has assumed the position of Director of the ATRC and the Rehab Engineering Department. Dr. Rosen brings to this position a wealth of experience in rehab engineering. Dr. Rosen comes to us from the University of Tennessee Memphis where he was an Associate Professor and Director of Graduate Studies and Director of Research. Prior to this Dr. Rosen was a Principal Research Scientist at MIT.

A copy of Dr. Rosen's C.V. was sent to Jean Shinbur, contracting officer to become part of our official file.

ATRC <u>Rehabilitation Engineering</u> Year 4 Annual Report, November, 1997

Biomechanical Analysis of Scott-Craig Type Long Leg Braces During Ambulatory Tasks

Project Number: 1 Status: Closing

Principal Investigator: Tom Dang

Co-investigators: John Noiseux, Brad Blaise, Joyce Luncher

Person-months committed: 7

Progress in Year 3:

The aim of this project is to obtain a quantitative understanding of the mechanical loading of the Scott-Craig type long leg braces during various ambulatory and functional tasks. Two goals of this study were to provide information to both the orthotic industry to address the issue of over-design and to the composite brace research team to possibly assist with the development of future nonmetallic composite brace components.

In year 3, data was collected from controlled laboratory tests, pilot tests, and four trials with research subjects. The controlled testing and pilot testing data was used to evaluate both the experimental protocol and the data collection system. Results from these tests led to the modification of both the original protocol and data collection system.

By conducting controlled laboratory and pilot testing, the calibration phase of the experimental protocol was critically evaluated for validation purposes. Using a test Scott-Craig long leg brace, we created finite element analysis (FEA) models of the braces. The results from the FEA model correlated well with experimental test data from orthosis uprights. As a result of our critical analysis of the procedure, the decision was made to remove the calibration phase of the experimental protocol.

The original intent was to obtain absolute forces and moments that a brace walker would generate during ambulatory tasks. After analyzing the first two data sets acquired from human subjects, the research team realized that absolute forces and moments could not be accurately measured due to several factors. Instead, absolute and relative *stresses* will be calculated from the strain gage data and will be used to estimate the moments during ambulation.

After encountering noise problems and determining the source, we also made the decision to design and construct a second-generation data collection system. The new redesigned system was built on printed circuit boards (PCBs) to minimize noise and improve the quality of the signal. The PCB design was contracted to a local company and the original design remained unchanged. The data collection system is still able to collect and multiplex up to 64 channels of data analog data at a maximum of 50 Hz by a single, 16-channel data-acquisition card (National Instruments, Inc.). A LabVIEW program written specifically for this project controls the system.

With the collection system complete, strain gage data has been collected for a total of four subjects (MA, WC, TM & GS) over the course of year 3. The data sets for all four subjects have been reduced and preliminary analysis has been completed. The original study planned on collecting data from 10 subjects, but we have decided to collect data from only 4. The rationale was that such dramatic differences were found among the four subjects tested that it was clear that a much larger sample than 10 would be required for meaningful statistical cross-subject analysis. Given the one week or more of two staff members and instrumentation cost required for each subject, a decision was made that equally useful suggestive information could be gleaned from 4 subjects as from 10.

Proposed Work and Outcomes for Year 4:

For year 4, the research team expects to complete analysis of the data sets from the four subjects and publish the results of the study. After preliminary review of the data, it appears that the results indicate maximum stresses occurring just above the ankle joint on one or both (left and right) braces for all users. The relative and possibly absolute stresses will be computed and reported for the following sites: below the ischial band, above the knee joint, below the knee joint, and above the ankle joint.

Clinical Study of Injection Molded Composite Ankle Joint Component of NRH Brace

Project Number: 2a Status: Closing

Principal Investigator: John Noiseux

Co-investigators: Tom Dang, Fatemeh Milani (NRH staff physiatrist), Ginger Walls (NRH

PT)

Person-months committed with Project 2b: 1.5 (of ATRC engineering staff)

Progress in Year 3:

In year 3 the second generation Ankle Joints (the previous version was not injection molded) were mounted in training braces at NRH. Clinical trials began in June and as of October 1st, were 60% complete (~30 of the 50 required clinical hours of use have been completed).

Proposed Work and Outcomes for Year 4:

As of November 20, 1997 97% of the required clinical time is complete. It is anticipated that this phase of testing will be complete by November 27, 1997. Upon completion of clinical trials the joints will be sent back to Sparta, Inc. where they will undergo post-clinical testing to verify that they have maintained their structural integrity. It is anticipated that the ankle project will reach closure by March of 1998.

Clinical Study of Composite Footplate Component of NRH Brace

Project Number: 2b Status: Closing

Principal Investigator: John Noiseux

Co-investigators: Tom Dang, Fatemeh Milani, Ginger Walls

Progress in Year 3:

The composite footplate has completed the initial design phase. Initial prototypes of composite footplate were fabricated by Sparta, Inc. and incorporated into orthopedic shoes by Nascott at NRH. These prototypes underwent mechanical testing at Sparta, Inc. but failed to meet established loading criteria. Design revisions to meet loading criteria and to facilitate incorporation into braces were begun.

Proposed Work and Outcomes for Year 4:

Completion of design revisions is expected. It is expected that second generation footplates will be fabricated and incorporated into orthopedic shoes for use in clinical trials at NRH. Units for clinical trials should be delivered \sim 12 weeks after funding is approved, \sim 3/1/98. Clinical trial pace will need to be faster than for the ankles, in order for the footplates to complete clinical testing with time left over in yr 4 for post-clinical testing at Sparta.

Endoprosthetic Replacement Surgery for Distal Femoral Sarcomas: Identification of Functional Outcome Variables and the Development of a Preliminary Knee Model for Presurgical Planning

Project Number: 3 Status: Closing

Principal Investigator: Tom Dang

Co-investigators: Justin Carter, Melanie Brown Person-months committed: 2 (including Dr. Brown)

Progress in Year 3:

The objectives of this study are, 1) to identify biomechanical function variables that best correlate to functional outcome measures as defined by the MSTS evaluation protocol for limb sparing procedures, and 2) to evaluate the feasibility of using a 3-D model of the knee to predict biomechanical function (related to functional outcome) variables in patients who have undergone the limb-sparing procedure for femoral osteosarcomas. Isometric tests were conducted to evaluate actual knee function along with kinematic and kinetic data obtained using the VICON 3-D motion analysis system. Functional tasks under investigation were a) level walking; b) stair ascending and descending; c) standing on one foot; and d) sit-to-stand. Data will be analyzed to derive patterns.

In year 3, the research team wrote the experimental protocol and submitted the proposal for IRB human consent approval. After IRB approval was granted, data collection was initiated. After the first few subject data collection sessions, the standing on one foot task was deleted because subjects found this task prohibitively difficult. Also, the second objective of the study (modeling) was abandoned because of difficulty obtaining values from MRI images for muscle insertion locations crucial in the development of a knee model.

We collected data for 7 subjects who had undergone distal femoral limb salvaging procedures. The motion and strength data was reduced and is currently being analyzed for 7 subjects. One method used to analyze the data was a simple one way ANOVA used to compare the average intersegmental angles and moments generated by the affected limbs during level over-ground ambulation to those generated by the unaffected limbs. The preliminary results were presented at ISOLS >97 and ASB >97 conferences.

Proposed Work and Outcomes for Year 4:

The plans for year 4 are the following: complete data analysis of 3-D kinematic and kinetic data and compare with strength test data to determine any correlation between data sets and published results. No additional subjects will be recruited.

Biofeedback/Augmented Therapy

Project Number: 4 Status: continuing/new

Principal Investigator(s): Tom Dang, Vineet Gupta

Co-investigator(s): David Brennan, Mike Rosen, Melanie Brown (consultant)

Person-months committed: 13

Progress in Year 3:

In year 3, a pilot study titled, "Video Games for Lower Extremity Strength Training in Pediatric Brain Injury Rehabilitation," was planned. The objectives for this study are: 1) to use instrumented video game-enhanced exercise programs to increase lower extremity muscle strength and control in children with brain injury, 2) to demonstrate that lower extremity muscle strengthening improves function in this population, and 3) to demonstrate that functional improvements are significantly greater when instrumented video game exercise programs are used in addition to conventional rehabilitation programs, as compared to the use of conventional rehabilitation programs alone. In the planned study, children with brain injury who are participating in a conventional rehabilitation program will be asked to use a video game driven from processed surface EMG for thirty minutes, three times per week to strengthen the weak muscles in their lower extremities. Baseline functional status and changes in functional status will be evaluated using a number of qualitative and quantitative methods. Traditional tests such as manual muscle evaluations and clinical questionnaires will be administered by clinicians and used to evaluate functional status. These evaluations will be supplemented with temporal spatial, kinematic, kinetic, and EMG movement analysis data obtained in the Performance Diagnostic Laboratory.

Also in year 3, the video game interface was designed, built and tested using a signal processing circuit consisting of an instrumentation amplifier, a RMS to DC converter, voltage comparator, and relay. Disposable passive EMG electrodes were used to measure muscle activity, and the circuit was interfaced into a Super Nintendo hand controller. The circuitry was built and tested successfully with some adolescent CP and SCI patients and the necessary components (leads, electrical equipment, etc...) for ten experimental units were purchased. The design and fabrication of printed circuit boards (PCBs) was contracted out, and all ten units were assembled into self-contained boxes. Presently eight are in working condition. In addition, Nintendo donated twenty Super NES units for testing.

In July of 1997, both MRI and the Dept. of the Army granted IRB approval. However, after several discussions, the research team identified several problems with the original experimental protocol outlined in the approved proposal. Some problems are as follows: current IRB approval applies only to subjects tested at NRH, a limitation which is impractical and must be overcome; and the over-ambitiousness of the functional outcome measure defined in the original proposal. The original proposal identified the functional outcome measure to be improved gait. However, it has been decided that a more realistic outcome measure might be improved strength of the targeted muscle groups as an objective measure of the effectiveness of the video game based therapy.

Proposed Work and Outcomes for Year 4:

For year 4, the research team proposes to complete a pilot test of a modified test protocol. After several research team discussions, the test protocol will be modified to indicate that isometric strength testing will be the outcome measure for the video game based therapy. In addition, the modifications will be amended and resubmitted to meet IRB approval. The remaining Super Nintendo controllers are to be modified so that there are eight complete working systems, and a library of games will be created so as to determine which games work best with the system. A method of measuring strength, as the functional outcome, possibly a hand-held dynamometer, will be identified, tested and incorporated into the experimental protocol.

Assessment of Unilateral Spatial Neglect in a Virtual Reality Environment

Project Number: 5 Status: closing

Principal Investigator: Justin Carter

Co-investigators: Joyce Luncher, Santosh Kodgi (Physiatry resident), Brendan Conroy,

William Garmoe

Person-months committed: 2.5 (of ATRC engineering staff)

Progress in Year 3:

The primary focus of year 3 was on collecting data from subjects in both of the original subject groups: the neglect group (NG) and the control group (CG). We collected data from 22 new subjects, which brought the overall total (after dropping 8 non-age-matched controls from year 2) to 24. The two major changes in the project protocol were 1) adding a Stroke-Only group (SO) of subjects who had a stroke but did not exhibit signs of neglect, and 2) reducing the number of subjects per group from 15 to 10. The first change was made to ensure that differences in performance between the two original groups (NG and CG) are in fact due to the neglect, and not simply from having had a stroke. The second change was made because the project was intended as a pilot study, and 10 subjects should be sufficient to gather data revealing the presence of any strong effects. At the end of year 3, we had tested 9 subjects in the Neglect group, 6 in the Stroke-Only group, and 9 in the Control group.

The secondary focus (towards the end of year 3) was on the initiation of data reduction. We constructed several Excel macros and C programs to organize and reduce the raw data. The reduction has just begun at this writing and has not yet yielded statistically significant results.

Proposed Work and Outcomes for Year 4:

In the early part of year 4, we will get approval from the IRB committee to continue the study and finish the data collection (1 NG, 4 SO, 1 CG). Once the data are collected, we will begin the reduction and analysis in earnest. The analysis will be done in several different ways (e.g. data analyzed for each cylinder individually, for cylinders grouped by location, etc.) and will use different outcome measures (e.g. distance of fingertip from actual cylinder center, root mean square error, etc.). The goal of these analyses will be to determine which of the cylinder locations/stimuli elucidate a difference between the Neglect group and each of the other two groups. The final outcome will be a paper including the results, conclusions, and suggestions for improvements for future studies.

The Development and Evaluation of Alternate Educational Strategies for Families of Patients with Unilateral Spatial Neglect

Project Number: 6 Status: closing*

Principal Investigators: Justin Carter and Katie Byers (consultant)

Co-investigator(s): Joyce Luncher, Patricia Fletcher, Melissa Richman (SLP consultants),

Brendan Conroy, William Garmoe

Person-months committed: 1.5 of ATRC engineering staff

Progress in Year 3:

The first 10 months of year 3 were spent preparing the virtual reality (VR) and video taped (VT) educational conditions. The VR condition was completed in March by iterative modifications of the three simulations. The VT condition was completed in July after editing and finalizing the script, incorporating clips from another video tape on neglect, finding an appropriate patient to film, and having the film professionally edited.

Collection of data, in the form of responses to questionnaires, from subjects in the VR, Control, and VT groups began at the end of March, beginning of April, and middle of July, respectively. Thus far we have tested 4 subjects in the VR group, 3 in the VT group, and 4 in the Control group. Subjects were family members of inpatients from the stroke unit.

Proposed Work and Outcomes for Year 4:

In year 4 we expect to continue data collection and to do some preliminary data analysis. Based on the rate of data collection (limited by subject availability) thus far (11 subjects in 8 months) we will be done collecting data in April 1999 (hence the * next to the "closing" designation above). At the end of year 4 we expect to have tested 24 (8 per group) of the necessary 30 subjects, and completed a preliminary analysis of the first 6 per group.

Motor Learning from Training in Virtual Environments

Project Number: 7 Status: New

Principal Investigators: Vineet Gupta, Justin Carter

Co-investigators: Jovce Luncher, Corrina Lathan (via CUA contract)

Person-months committed: 10 (of ATRC engineering staff)

Background:

The Department of Defense has been using computer simulations for training troops (flight simulators, tank simulators, etc.) and also for mission planning and weapons evaluation. NASA has also been using virtual reality (VR) simulations for training astronauts for space flights and repair missions. In the civilian sector, VR has been used for training pilots, operators of large ships, etc. Training individuals in VR environments that simulate real world environments is advantageous as it does not have the hazards to equipment and lives associated with the "real world". However, there is little experimental data available about the transfer of training from VR environments to real world environments. The objective of this study is to perform an objective evaluation of the transfer of training and of the particular features of a VR training environment which promote effective transfer.

Learning in any environment has been classified under four headings: (1) procedural learning, (2) perceptual motor learning, (3) spatial learning, and (4) navigational learning. The proposed study will address the issues pertinent to transfer of training in the second and third types of learning.

Proposed Work and Outcomes for Year 4:

The experimental protocol for this project is currently under development. The basic idea of the research is to develop virtual and physical environments constituting the same task in which to train and test subjects. The study will comprise two groups: (1) Subjects trained in the virtual environment and (2) Subjects trained in the physical environment. The former subjects will include four subsets whose training simulations include (a) only visual displays, (b) visual and auditory displays, (c) visual and tactile displays, (d) all three. All will be tested on the real world tasks for which they were trained.

The results from this study should provide measures of the motor and spatial learning of subjects in the two environments from which indices of transfer of learning from virtual to real world environments can be computed. The results may also permit conclusions regarding the dependence of training transfer on simulation display features. This study should have spin-offs into other ATRC VR studies.

Motor Control in Stroke Patients, Studied with Virtual Reality Technologies

Project Number: 8 Status: Continuing

Principal Investigator(s): Corrina Lathan (under CUA contract) and Vineet Gupta Co-investigator(s): Justin Carter, Joe Bleiberg, Alex Pouget (uncompensated psychology research consultant from Georgetown U), and Zui Wang (CUA graduate student) Person-months committed: 1.5 (of ATRC engineering staff)

Progress in Year 3:

Lesions of the parietal cortex damage selectively the ability of patients to perform spatially accurate hand or eye movements while sparing their ability to identify or name objects. The objective of this study is to determine how such patients perform hand and/or eye movements towards visual and auditory targets generated by virtual reality systems. This is an example of a particular use of VR in rehabilitation, i.e. the application of state-of-the-art simulation technologies to provide particularly rich and easily modified experimental stimuli for research which would be difficult to accomplish otherwise.

An initial version of the software to generate visual targets was written to run on the ONYX. The biggest barrier to progress this year has been the equipment integration. Delivery of the V6 HMD with the integrated EyeTracker was delayed by ISCAN from July to late November. Also, we have placed an order for the Audio Serial Option (ASO) from SGI to incorporate sound and additional serial ports into the ONYX

Proposed Work and Outcomes for Year 4:

Once the ASO is here and the V6+Eye Tracker has been tested and calibrated, all the equipment can be integrated with the ONYX. The complete software (with visual and auditory targets) will be developed. Initially pilot data on control groups/normal subjects will be evaluated on the system to determine the finer modifications that need to be performed on the testing protocol. Once the testing protocol is well defined, stroke patients (with parietal lesions) will be tested in Year 4.

Flock of Birds and the CyberGlove will be used to acquire the hand movement data and the EyeTracker will be used to transduce angle of gaze. Data will be collected from 10 patients and 10 normal subjects.

The results from the study are expected to provide insight into how the brain stores spatial representations. If the representation for the eye and the hand is shared, then the patients would have the same problem in moving their hand and eyes to the target locations. If the representation is distinct then there will be situations in which the patients will be able to perform an eye movement but not a hand movement to the same target, and vice-versa.

Surgical Excision of Lower Extremity Soft Tissue Sarcomas: Ability of a Computer Model to Predict Deficits in Strength and Function

Project Number: 9 Status: new

Principal Investigator(s): Justin Carter and Dr. Martin Malawer (WHC orthopedic oncologist)

Co-investigator(s): Tom Dang, Brad Blaise, Dave Brennan, Robert Henshaw (WHC orthopedic oncologist)

Person-months committed: 8 (of ATRC engineering staff)

Background:

One innovative method for treating soft tissue sarcomas in the lower limb is the radical resection of the entire muscle or muscle group. While this method has the same success rate as amputation (in terms of infection and local recurrence), post-surgical functional task performance has not been characterized. The goals of this project are 1) to determine the reduction in strength (the force a patient can exert using the limb) due to the muscle resection, 2) to investigate whether the reduction in strength results in changes in functional task performance, and 3) to test the validity of a 3-D computer model's prediction of the reduction in strength.

Proposed Work and Outcomes for Year 4:

The first goal will be accomplished using a dynamometer. Total isometric torque across the subjects' joints on the involved and uninvolved sides will be measured, and the fractional reduction of torque resulting from the muscle resection will be calculated.

The second goal will be accomplished using motion analysis. Subjects will walk over level ground at a self-selected speed, walk up a step, and rise from a stool. The kinematic and kinetic data from the subjects will be compared to those from healthy walkers.

To accomplish the third goal, the fractional loss in total joint torque will be compared to the normalized prediction provided by the Software for Interactive Musculoskeletal Modeling (SIMM®). SIMM's total joint moments are computed by calculating joint moments produced by individual muscles, and summing them. Although the SIMM calculations of *total* joint moments have been validated elsewhere through strength testing, the predictions of individual muscle moments have not, since it is impossible for intact individuals to contract individual muscles within a synergistic muscle group. Single muscle resection provides an opportunity to add to the body of validation data.

Outcomes from this study will be the knowledge of strength loss post-surgically and how this loss affects function in terms of compensatory strategies, as well as a test of the validity of the model. The value of the strength and gait information lies in future planning for both the surgeon and rehabilitation professionals. The value of the software validation lies in its potential for constructing patient-specific computer models and pre-surgical planning tools for surgeons.

Tele-ANAM

Project Number: 11 Status: New

Principal Investigator: Vineet Gupta

Co-investigators: Tom Dang, Brad Blaise, Joe Bleiberg, and Corrina Lathan (under CUA

contract)

Person-months committed: 5.5 (of ATRC engineering staff)

Background:

Certain medications may have positive or negative effect on patients' cognitive performance, not directly related to the medical conditions for which they were prescribed. Similarly, soldiers can also undergo adverse psychological changes due to exposure to hostile battlefield situations (e.g., desert conditions in Iraq). The army has been using Automated Neuropsychological Assessment Metrics (ANAM) to measure aspects of the thinking acuity of these soldiers. As currently administered, the assessment battery requires that the soldiers perform tasks at a computer keyboard. The reaction times of the soldiers while responding to stimuli is measured and used for determining their cognitive status. Recently, Joe Bleiberg and his ATRC group have been using ANAM for assessment of patient function as affected by cognition-enhancing agents like Gingko. However, for the tests to be performed on the subject, either the subject has to travel to the testing facility or the personnel performing the test have to go onsite. This testing procedure cannot be performed on a frequent basis especially in situations where the travel time and expenses are a governing factor. Therefore, there is a need to develop a telediagnostic system that can measure reaction time of the subjects from a remote site using only the phone itself as the testing instrument. The objective of the present study is to develop a telephone-based telediagnosis system that can perform reaction time measures over the telephone line.

Proposed Work and Outcomes for Year 4:

To develop this system the first step is to determine the transmission line delays in the telephone system. Tests performed at the ATRC have shown that the transmission delay within D.C. area is microseconds or less. At present we are determining the transmission line delay from different states. The next step will be to perform tests over the telephone line to determine reaction time of normal subjects. The testing facility will place a call to the subject at a remote site. The subjects will be asked to press a key on their telephone keypad as soon as they hear a tone transmitted from the testing facility. The transmitted tone and the received key press will be used to determine the reaction time. The reaction times of the subjects tested via computer-administered ANAM and over the telephone will be compared to form a baseline measure for reaction times over the telephone. An automated system (hardware and software) will next be developed that will administer the battery of ANAM reaction time measurements over the telephone line. Year 4 will be devoted to the development of the system and testing it on normal subjects. Measurement of reaction time on patients is also expected to begin in Year 4.

Boing! — a Home Exercise Arcade for Children with Disabilities

Project Number: 15 Status: New

Principal Investigators: Dave Brennan, Joyce Luncher Co-investigators: Mike Rosen, Melanie Brown (consultant)

Person-months committed: 11.5

Background:

Before coming to NRH, Mike Rosen taught a graduate course called Product Design for People with Disabilities in the School of Biomedical Engineering at the University of Tennessee, Memphis. In this hands-on course, the students were assigned a new problem each year, always in the form of a brief description of an unmet need of a particular population of people with disabilities. In the Spring of '96, the students designed and built an exercise system for children with disabilities which could be used for aerobic exercise or resistance exercise for any body part in any direction — at home or in the clinic. UT Memphis graduate student Gary Downey extended the work through a year of MS project work and is currently drafting his thesis on the results.

The UT students designed a device they labeled Boing! because it is based on a single bungee cord. The system is an "exercise arcade" in that it provides a multi-purpose home gym for children in which every exercise is performed in the context of a computer-generated video game. Boing! is composed of a tubular steel frame which looks roughly like two St. Louis arches leaning against each other at the top and braced at their bottoms on a circular base. The diameter of the base is about fifty inches and the frame stands about sixty inches high. The bungee cord is suspended at the top of the frame from a sensor fabricated from the components of a standard computer mouse. When a child pulls on the bungee cord in the course of an exercise, this transducer detects the stretch in the cord and transmits a proportional change in signal to the computer. The computer's screen is attached to the frame where it can be seen by the child. Every move the child makes is reflected in a change in the image on the screen. For example, in an arm extension exercise set up in the original prototype, the game software showed a moving vacuum cleaner which advanced across the screen in synch with the child's arm movements. If the child pushed hard enough and stretched the cord enough to move the vacuum all the way across the screen, funny objects which had fallen into its path (frogs, grandfather clocks, ...) got sucked into it causing the vacuum to shake and belch. In this way, what the therapist views as an exercise is perceived by the child as a game, one that s/he wants to play just for the fun of it.

Gary Downey's prototype is presently in evaluation at the Campbell Clinic in Germantown, TN. Discussions with a company interested in commercializing it are in progress and the University of Tennessee Research Center (UTRC, the UT technology transfer arm) has submitted a patent application.

Proposed Work and Outcomes for Year 4:

With the enthusiastic approval of UTRC, Joyce Luncher and Dave Brennan will be building a new Boing! prototype and evaluating it with children through contacts with NRH staff pediatric physiatrist Dr. Katherine Alter and other colleagues at Children's Hospital National Medical Center and Hospital for Sick Children. ATRC staff will also have the assistance of Johns Hopkins Physiatry consultant Dr. Melanie Brown. Several detailed modifications are expected in the mechanics of the system, in particular means of reducing binding of the bungee cord where it changes direction around pulleys between the overhead transducer and the exercising limb. Increased attention will also be given to design for manufacture. The new prototype will be placed for daily use by therapists in a pediatric rehabilitation setting (to be determined). A protocol will be established for collecting data on its efficacy in meeting therapeutic goals as well as reactions of therapists, children and their families. Since Boing! is expected to provide the motivation needed for consistent compliance with exercise protocols, and because the link to a computer simplifies capture of objective use data, the ATRC will also use it as a means of studying aspects of the physiology of exercise in children with cerebral palsy.

Ani-Mate: a Software Environment for Creating Custom Video Games for Use with Boing!

Project Number: 16 Status: new

Principal Investigator: Justin Carter

Co-investigators: Dave Brennan, Tom Dang, Mike Rosen

Person-months committed: 6

Background:

To succeed as a product, Boing! will need to rely on the availability of a large collection of animated games which will be sufficiently engaging to exercising children to motivate their efforts. While ATRC Project 4 is exploring the possibility of using standard video games for biofeedback, this project will investigate the feasibility and potential of a field-programmable software system which will allow therapists and parents to create *custom* games for each user. This will be particularly important for Boing! users for several reasons. Some will be much younger than the age group at which most video games are aimed. Even for older Boing! users, cognitive or experiential limitations may make it essential to match the characteristics of a game to his/her abilities. In particular, control over the degree of abstraction inherent in the mapping from the user's limb motions to the events on the screen may be critical if the child is to understand it and interact with it. Also, capturing a child's attention sufficiently to motivate repetitive exercise over a period of many weeks might be expected to depend on the ability of a game to incorporate his/her favorite objects, situations, music, etc.; and on the degree to which the game includes the element of surprise, i.e. unpredictability. For all these reasons, the ATRC proposes to devote project 16 to the development of Ani-Mate, a software tool with which an adult with no specialized knowledge of computers can craft individualized animated computer games.

Proposed Work and Outcomes for Year 4:

As the ATRC engineers currently imagine it, the Ani-Mate interface will be menu-driven, i.e. a therapist contemplating a particular exercise for a specific child will respond to queries from Ani-Mate regarding the particular user and the exercise. From the therapist's responses, this program will synthesize a custom game which should be within the child's cognitive capacities, avoid puzzling or startling stimuli, engage his/her sense of humor by including favorite objects and situations, and offer on-screen rewards for successful completion of the desired number of rep's. The commercial development program we have settled on is Director because of the favorable outcome of early efforts in game software development by Dr. Stan Cronk at UT Memphis. The coming year's work will include:

- Development of the game authoring software to the point where the system can be demonstrated with a limited range of standard game metaphors.
- Development of a prototype of the clinician interface which is ready for evaluation by clinical colleagues at NRH to test the extent to which its use is self-explanatory. This task will also require identifying the most important questions for characterizing the individual child and exercise.
- Incorporation of five standard game metaphors, e.g. vehicle steering to collide with a fixed target; punching or kicking a fixed target; moving a child icon to evade a pursuing creature; etc.
- Building an initial graphical database of favorite moveable objects and targets which can be incorporated into standard game metaphors to generate custom games.
- Designing an initial version of a knowledge base which draws conclusions regarding the permissible cognitive demands of a game from the clinician's answers to interface queries regarding the child's capabilities.

Boogie Button: Making Powered Wheelchairs Dance

Project Number: 17 Status: New

Principal Investigator: Mike Rosen

Co-investigators: Brad Blaise, Justin Carter, Vineet Gupta, John Noiseux

Person-months committed: 7.5

Background:

The primary rationale for this project is simply that most people enjoy music and many like to dance — or would if they could. People who use powered wheelchairs may be no exception, and in fact needn't be excluded from the joy of rhythmic movement since dance-like moves and sequences of moves are certainly within the capability of their vehicles. In fact, even for individuals whose disability is severe enough that accurate dynamic control (or *any* control) of a powered chair is beyond their capabilities, the chair has potential as a "ride" (or automated dance partner), i.e. as a source of enjoyable motion in which one can be a passive but appreciative passenger. It may also be the case that there is therapeutic value to "chair dancing" for some individuals, for example suppression of spasticity through vestibular stimulation. (Anecdotal evidence regarding this kind of effect from horseback riding and boating is commonly reported.) And of course for anyone whose disability limits opportunities for socialization and its value to development, being able to attend a school dance can foster valuable contact with friends.

What we propose is the development of a product which will make it possible for a powered wheelchair to dance. This project is consistent with the ATRC's focus on design of new products and enhancement of human motor function.

Proposed Work and Outcomes for Year 4:

As presently conceptualized by ATRC engineers, the Boogie Button will consist of a custom-programmed micro-controller (packaged with a CD player for situations in which there is no ambient music) which will take over control of the wheelchair, temporarily replacing inputs from the standard control interface, and make it move through sequences of programmed choreographed movements, in time to the music. Chair dancers with disabilities which prevent accurate control will be able to turn the unit on and off through one big button which forms its top surface -- hence the name. The engineering design cleverness will reside in the software which detects the beat and stays with it. In some dance music, an obvious bass line or drum beat should make this straightforward. Music in which the relation of the rhythm line to the meter is more complex will require more a sophisticated algorithm in order to stay in synchrony and detect the "bar lines".

In addition to the on-off control, settings will be available to avoid movements which are expected to be frightening or trigger reflex patterns or create unacceptable mechanical loads in the dancer's neck or torso. Particular values of these settings will, of course, vary dramatically among individuals. An additional setting should also be possible to set approximate limits on the space within which the chair will make its moves to avoid collisions with walls, objects or other dancers.

ATRC engineers intend to consult with a choreographer or professional dancer for this project, as well as with NRH PT and OT staff. A prototype of the Boogie Button should be ready for demonstration by Summer of '98.

Project Title: Wired Independence Square

Project Number: 19 Status: new

Principal Investigator(s): Brad Blaise

Co-investigator(s): Vineet Gupta, Anthony Fu

Person-months committed: 6

Background:

Construction is currently underway at NRH on Independence Square, a section of the hospital which will contain full-size working mock-ups of the interiors and exteriors of everyday living spaces — a four-room apartment, bank, diner, market, automobile, and street. A commercial product of Guynes Design, Inc., this area will be used to train disabled patients in adaptation to environments which they will regularly encounter after they are discharged. The presence of Independence Sq. at NRH will provide ATRC engineers with an opportunity to work with clinical staff people to enhance the way functional assessment of rehabilitation patients is undertaken. Traditionally, evaluation of a patient's performance during training is qualitative and therefore sensitive to inter-rater variability and subject to the limited resolution and shifting calibration which plague subjective ratings. Our desire, therefore, is to implement a sensor-based system in Independence Square that will permit therapists to quantify and store objective measures of the performance of a patient during his/her training in Independence Sq.

To make this a reality, ATRC engineers will work with clinicians in the Occupational Therapy and Physical Therapy Services to select the appropriate sensors, as well as to ensure that a clinician-friendly data acquisition and display software package is created.

If successful, the results should be appealing as a means of defining objective outcome measures and setting quantitative functionally-oriented criteria for discharge. This may prove to be as attractive to hospital administrators and reimbursement sources as it is to therapists.

Proposed Work and Outcomes for Year 4:

The need for continual, efficient communication between the ATRC engineering staff and the clinical staff is vital to the success of this project. The initial stages of the project will be more hardware oriented and will occur as construction on Independence Square nears completion in December '97 and January '98. Work done at this time includes the installation of the wall-jacks that the sensors placed throughout Independence Square will plug into. Also, cables are being installed in walls and routed from these wall-jacks through the ceiling to the central data acquisition room where all the data will be accessible to therapists for selection, formatting and annotation.

The selection of sensors will be the next task. They will be installed wherever needed to detect the functional events (e.g. opening a door, turning on a TV or stepping on a curb) and measure the relevant variables (e.g. hand force on a railing) which therapists define as characterizing their patients' functional gains. Many sensors will just be switches of various kinds. Closed-circuit video and digital still cameras will be installed to provide direct visual records of patients' activities. Continuous speech logging of clinician observations should also be possible as an additional data stream to the host computer. Although it is expected that the need for sensing of various kinds will evolve as therapists begin to use our Wired Independence Sq., the intent of this project in ATRC yr 4 will be to instrument a limited set of sites and functions to test feasibility and prepare a demonstration.

The final, and most difficult task, will be assembling all of the sensor information from all corners of Independence Square via one neat, clinician-friendly, menu-driven software package. The software will have to be versatile enough to allow for the collection and reduction of data from many different sensors at irregular intervals. It must permit therapists to access, select from and format data that has been acquired to prepare standardized digital records for their own use, for the patients, and for outside agencies. Incorporation of simple real time visual and/or auditory feedback to patients as they negotiate Independence Sq. will also be considered.

ATRC <u>Cognition and Performance Enhancement</u> Year 4 Annual Report, November, 1997

1. Efficacy of Ginkgo biloba (Egb 761) for Enhancing Neuropsychological and Daily Functioning after Stroke.

This study will examine whether Ginkgo biloba (EGb 761), an herbal substance, enhances recovery of neuropsychological functioning and activities of daily living in persons who have suffered a recent stroke. Individuals to be included are those who had a recent stroke, are judged not to be at high risk for having potential medical side-effects of taking the herb, do not have a premorbid neurologic or psychiatric condition, and who are able to give informed consent. In a 6-month, double-blind, randomized, placebo-controlled, parallel group clinical trial, approximately 550 subjects will be randomly assigned to one of two conditions: ginkgo (experimental) or placebo (control). Indices of neuropsychological performance, functional independence, general medical health, psychological well-being, quality of life, and stroke severity will be obtained before initiation of treatment and approximately 8 weeks and 6 months later. Repeated measures ANOVAs will be computed to assess whether ginkgo enhances the rate of recovery, above and beyond that of spontaneous (natural) recovery and rehabilitative intervention. It is estimated that 550 subjects will be enrolled in the study.

2. Sports Concussion Study

During Year 2, a proposal to study patterns of recovery from sports-related concussion was approved. In Year 2, a collaboration with the athletic departments of Gonzaga College High School (private, Jesuit, boys) was arranged. In Year 3, we were able to arrange to collaborate with Elizabeth Seton High School (private, Catholic, girls). In addition, revisions were made to the protocol to include control subjects: college-age, non-athletes, with and without a history of prior concussion, at Catholic University of America. During Year 3, a total of 87 subjects were enrolled, 66 of whom were high school athletes, and 22 were control subjects. Of the high school athletes, 14 were female and 51 were male. One subject dropped out when he left the football team. One subject received a concussion playing football shortly before the start of the study. One subject, also football, was suspected by the team coach of having had a Grade 1 (the mildest grade) concussion during the season and was given a post-concussion assessment. No evidence of impairment was noted and the subject was not followed further.

Due to the absence of new concussions, we decided to look at subjects based on prior concussion history. Of the 61 subjects completing both baseline and follow-up assessments, traditional neuropsychological tests showed very few consistent differences between subjects with histories of prior concussion and those without. The football players with prior concussion performed more poorly on ANAM at baseline assessment, but were comparable with those without prior concussion by follow-up assessment at the end of the football season.

In order to maximize the number of new concussions we can study, the focus of this study is changing from a team and school-based approach to a city-wide, risk-based approach. Beginning in Year 4, at-risk participants are being recruited from Gonzaga and Elizabeth Seton High Schools and also via newspaper announcements and mailings to area high schools and houses of worship. In this context, "at-risk" means that a child is currently or soon to be engaged in an athletic activity known to result in concussions to some players in a typical season. At-risk activities include football, soccer, lacrosse, hockey, roller blading, horseback riding, skateboarding, and other similar sports.

During Year 3, collaborations with Jim Kelly at Northwestern, studying the Chicago Bears, and Dennis Reeves at Balboa, studying high school football players, were initiated. In Year 4, data from these studies will be integrated with NRH data using the ANAM database to facilitate comparison across subject pools and protocols.

3. Factors Influencing Stability of ANAM Performance

The question of stability of cognitive performance following brain injury has become of increasing significance relative to several issues. First, difficulties establishing stable baseline performance in subjects with traumatic brain injury (TBI) has made it extremely difficult to pursue single-subject medication trials. Unstable performance baselines interfere with the ability to identify potential medication effects (e.g., to separate 'noise' from possible drug response). Second, our recent group study of 6 mild-TBI and 6 normal controls suggested that performance instability may be a salient feature of brain injury in some subjects. This possibility has not been explored systematically in the research literature up to this point. Third, it is important to be able to demonstrate that ANAM does provide stable baseline acquisition data. Extensive discussion of these issues at the 1996 Consensus Conference and in subsequent meetings resulted in development of a protocol to address these issues. The study has been approved and data collection has begun as of September 1997.

Twenty TBI and twenty normal control subjects will undergo repeated testing using the ANAM battery. Half of each group will undergo a massed-trials (MT) acquisition schedule, while the other half will undergo distributed-trials (DT) training. The TBI and control groups will be compared for speed and consistency of ANAM performance. The MT and DT training schedules will also be compared to determine whether one produces a more stable performance asymptote.

4. Psychometric Properties of ANAM

Despite the wide availability and use of ANAM, few norms have been established for its use as a repeated measures instrument. To improve its use as both a research and clinical tool, reliability and validity analyses will be performed during Year 4. Early analyses suggest that while multiple trials of ANAM tend to generate performances in similar reaction time and accuracy ranges, there may be some trials which are noticeably easier or more difficult than others. In Year 4, item and factor analyses will be utilized to investigate internal consistency and the possible presence of types or collections of stimuli which limit ANAM's ability to differentiate among subject groups. Using the ANAM database, external sources of ANAM data will be incorporated into these analyses. Dependent on the outcome of these analyses, a proposal to generate changes to ANAM stimulus tables and run parameters will be developed as appropriate.

During Year 3, an item analysis of existing data from the Mathematical Processing task suggested the presence of two types of stimuli in each trial. Theoretical interpretation of the data suggested that different cognitive processes might contribute to differential in performance on these two types of items. Several pilot subjects completed a protocol designed to test this hypothesis using a revised stimulus set for the Mathematical Processing Task, and a special training protocol. In Year 4, this data will be analyzed and, if there is merit, a proposal will be developed to investigate this phenomenon and other response patterns which could provide ways to make ANAM more sensitive to group performance differences.

5. ANAM Database

Research using ANAM as a repeated measures test generates enormous quantities of data. It was determined during Year 1 that a centralized ANAM database could greatly facilitate the data reduction and analysis process and facilitate collection of data from colleagues in the ANAM research community. In the latter portion of Year 2, a Microsoft Access database was designed and developed to store the raw ANAM data and associated demographic and neuropsychological test data collected by researchers here at NRH. In Year 3, the testing and demonstration phase included data entry and data management of neuropsychological, psychosocial, demographic, and ANAM data from earlier studies (Variability and Ritalin/Dexedrine), the Sports Concussion Study, several ATRC pilot projects, and from samples provided by colleagues at Baltimore VA and Balboa Naval Hospital. Expansion of the database to include additional ANAM tasks from the Tester's Workbench continues, incorporating design features which will enable a more generalized approach to ANAM data management in the future. Based on design incompatibilities uncovered during testing with new ANAM batteries, general distribution to the ANAM community and researchers at large has been postponed and is now part of the Year 4 plan. Enhancements currently in progress and in the design phase include comprehensive processing of ANAM run parameters. acceptance of non-numeric id numbers, an internal id manager to permit composite data samples to be formed by combining subject data across studies and sources, and more sophisticated security features. All new design features will be documented in the existing manuals. Once the database has been fully tested and is in a stable form, preparations will be made to make it available on a server and ultimately via the World Wide Web. A protocol will be developed to allow the larger ANAM research community to add data to the database and to access the data of others.

6. ATRC - Cognitive Studies Web Page

In order to facilitate the use of ANAM among researchers in diverse locations, the possibility of placing the ANAM Database and related literature on the Internet was introduced in Year 2. In Year 3, discussions yielded the following needs for web page content:

- ANAM Database approved users would be able to upload their data and access data from other sources;
- ANAM (and related) References a citation list of published articles, technical reports, and researchers working with ANAM;
- Description of ATRC Cognitive Studies activities and biographies of investigators
- Recruitment calls for subjects for ATRC studies
- Bulletin board, chat room, and/or Listserv to facilitate discussion of ANAM-related topics.

During Year 4, an appropriate server will be identified (ATRC Rehab Engineering) and appropriate personnel will be hired or trained to design and develop the site. After in house demonstration and testing, the site will be made available to web users.

7. Investigation of Grip Constancy as a Behavioral Marker of Concussion and Mild Head Injury

This is a new pilot study undertaken in Year 4. Patients with post-concussion and mild head injury, and three reference groups, one with schizophrenia, one with autism without mental retardation, and one without disability, will attempt to maintain constant levels of force grip on a hand dynamometer. Target force levels will be well below maximum grip strength. A tone will signal the patient when grip force has strayed outside the target range. The dynamometer will communicate with a computer for data acquisition.

Motor deficits of various kinds have been noted in patients with schizophrenia, including deficits in grip force constancy, which appears to be a reliable behavioral marker of this disorder. Patients with post-concussion, and patients with mild head injury, self-report clumsiness. Similarly, individuals with autism without mental retardation are noted in numerous clinical studies to show clumsiness. This study represents (1) a replication of an earlier study by A. Rosen and colleagues of grip constancy in schizophrenics, (2) and investigation of the utility of this task as marker of concussion, (3) an attempt to characterize and quantify some aspects of clumsiness in traumatic (concussion) and non-traumatic (autism) populations, both of whom are clinically described as "clumsy".

It is hypothesized that grip force constancy is impaired in concussion patients because of feedback deficits resulting from injury to frontal lobe white matter. If this task is a marker for concussion, it has useful clinical potential for assessment of recovery and determination of safety for returning to play contact sports. A second, less specific hypothesis is that study of the function of grip force (curve shape) may provide some indication of underlying processes in motor control in the patients groups.



DEPARTMENT OF THE ARMY

US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND 504 SCOTT STREET FORT DETRICK, MARYLAND 21702-5012 7/19/2000

REPLY TO

MCMR-RMI-S (70-1y)

6 Jul 00

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FOR THE COMMANDER:

Deputy Chief of Staff for Information Management